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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,603	06/08/2005	Tatsuhiko Kodama	14875-137US1	5647

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,603	KODAMA ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8 and 10-20* is/are pending in the application.

4a) Of the above claim(s) *1-3, 10-18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6-8 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Matters

1. The instant application has been transferred to a new examiner, which is Marcia Noble. Applicant's supplemental amendment, filed on 11/13/2006, that amends claims 4 is acknowledged. Applicant also amended claims 4 and 19 in an amendment filed 10/24/2006, which was filed in response to the Non-Final Rejection, mailed 4/24/2006. Applicant's remarks in response to the Non-Final Rejection, mailed 4/24/2006, are in the prior response, filed 10/24/2006.

Status of Claims

2. Claims 1-4, 6-8, and 10-20 are pending. Claims 1-3, 10-18 and 20 were previously withdrawn in response to a restriction requirement. Claims 4 and 19 are amended as previously discussed above. Claims 5 and 9 are canceled by amendment filed 10/24/2006. Claims 4, 6-8 and 19 are under consideration.

Oath/Declaration

3. The oath or declaration was objected to as being defective because only 2 or the 4 inventor signatures were present. Applicant submitted a new declaration, filed 10/24/2006 which is in compliance with 37 CFR 1.67 (a). Therefore the objection is withdrawn.

Priority

4. A certified translation of the foreign priority documents, filed 10/24/2006, submitted under 35 U.S.C. 119(a)-(d) is acknowledged and have been placed of record in the file.

Information Disclosure Statement

5. The information disclosure statement (IDS) was filed on 10/24/2006 after the mailing date of the Non-Final Rejection on 4/24/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. However, reference AH on page 1 of the IDS was not considered because it was not provided and reference AK on page 1 of the IDS was not considered because it was in a language other than English and therefore both references were crossed out.

Claim Objections

6. Claim 4, objected to because the claim was drawn to a gene expressibly encoding the background antigen, has been revised and no longer contains this recitation. Therefore the objection is withdrawn.

Drawings

7. The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Specifically, Figure 4 of the drawings includes sections labeled 30, 34, 46

and normal, however there is no explanation as to what these labels signify in the brief description of the drawings. Applicant amended the specification to more clearly explain what the above label mean in an amendment to the specification, filed 10/24/2006. Therefore the objection is withdrawn.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

8. Claims 4 and 6-8 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method for producing an antibody against an antigen, wherein the method comprises the steps of:
(a) preparing a baculovirus that comprises a DNA which encodes an antigen or an epitope thereof;
(b) infecting a host cell with the baculovirus of (a) to obtain a budding virus that expresses said antigen or an epitope thereof;;
(c) producing a transgenic mouse that expresses a gene encoding the baculovirus membrane protein gp64,
(d) immunizing the transgenic mouse of (c) with a fraction comprising the budding virus of (b); and
(e) recovering an antibody-specific for said antigen from the immunized animal.

, does not reasonably provide enablement for

A method for producing an antibody against a target antigen, wherein the method comprises the steps of:
(a) preparing an immunogen comprising the target antigen and any background antigen;
(b) producing any transgenic non-human animal comprising a gene expressibly encoding
any background antigen;

(c) administering the immunogen of (a) to the transgenic non-human animal of (b); and (d) isolating the antibody against the target antigen from the transgenic non-human animal.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant traverses this rejection on the grounds that the claims have been amended to recite transgenic mice rather than transgenic animal and therefore is fully enabled. Applicant further argues that contrary to the unpredictable transgenic animals disclosed in the art of the enablement rejection, the instant transgenic mice need only express as much of the antigen as required to induce immunotolerance and the art of the enablement rejection encompasses far more complex phenotypes than that the expression required to induce immunotolerance (see page 7 of remarks, filed 10/24/2006). Applicant also argues that promoter element necessary for expression of a transgene in the mouse are establish in the art and therefore are enabled.

Applicant's arguments are not found persuasive because overall the scope of enabled did not only encompass scoping the transgenic animal to a mouse but more specifically a gp64 transgenic mouse. However the breadth of the claims still read on a transgenic mouse expressing any background antigen. Furthermore, the scope required that step (a) be scoped to a baculovirus, whereas the breadth of the claims encompasses any immunogen that is a budding virus particle or part thereof.

As previously stated in the Non-Final rejection, the art of producing a transgenic mouse with a specific phenotype is highly unpredictable in the art. Therefore, an artisan would require specific guidance from the specification to overcome these obstacles

described in the art. The specification only provides this level of specific guidance in its disclosure of a gp64 transgenic mouse; therefore the specification only enabling for a gp64 transgenic mouse. Furthermore, as previously stated in the specification, the instant invention is a method that results in immunotolerance to a background antigen by expressing it in a transgenic mouse in a level sufficient to elicit an immune response and consequent immunotolerance. In the instant invention again the only transgenic mouse provided with adequate specific guidance is a mouse expressing the background antigen gp64, which is specific to baculovirus. Therefore, for the instant invention to function as disclosed, it must also provide baculovirus as it specific antigen and therefore the specification is only enabled for baculovirus as its immunogen.

In regards to Applicant's arguments, that fact that the art in the enablement requires more complex phenotypes to be expressed by the transgenic mice is not found persuasive because regardless of complexity the art suggests that obtaining any phenotype is highly unpredictable, ie-often times for various reasons no expression is encountered. Only when specific guidance is provided to the production of a specific transgenic mouse with a specific phenotype can this unpredictability be overcome. Again the specification does not provide this level of guidance for the breadth encompassed by the transgenic mice expressing any background antigen. Therefore, the specification is not enabling for a transgenic mouse expressing any background antigen.

Applicant's arguments suggesting that promoter element that function in mice are acknowledged. However, there are many more factors in involved in this instant

method that are affecting expression of the transgene such as integration, leakiness of expression system, etc...and also the method required an immunogen administered that is specific for the background antigen being expressed by the transgenic mouse. The breadth of the claims an compass an immunogen compatible or incompatible with the transgenic mouse expressing any background antigen. Therefore, regardless of the promoter element used other non-enabling factors are still involved in the instantly claimed method.

Therefore, because the amendment and Applicant's argument's do not overcome the rejection of record for claims 4 and 6-8. The rejection is maintained for these claims.

Claim 19 was originally encompassed in the instant rejection. However, the amendment to the claims overcame the enablement rejection. Therefore, the enablement rejection of claim 19 is withdrawn.

New Matter

9. Claims 4, 6-8 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Amended claims 4 and 19 recite "in an expressible manner". There is no literal support for this recitation. There is some figurative support because this recitation is in reference to a transgene that is meant to be expressed. However, the claims provide no functional elements to provide for a transgene expression and the recitation "in an expressible manner" does not provide these necessary functional elements needed to result in expression. Therefore, the recitation also lacks figurative support as well.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 4, 6-8 and 19 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The instant invention involves the expression of a vector comprising a transgene. However, for a transgene to be expressed effectively it must minimally comprise the elements to be directed by the transcription and translation machinery of the target cell which require a promoter capable of driving expression in the target cell. However, the instant claims only disclose "a gene encoding a background antigen in an expressible manner", "a gene encoding a PepT1 in an expressible manner", or "a gene encoding a baculovirus membrane protein gp64 in an expressible manner". Because of the necessity for the minimal elements necessary to drive expression of a gene, an artisan would not know how to use a nucleic acid encoding one of the above transgenes without operable linkage to a promoter, in transgenic mouse or baculovirus as claimed.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Amended claims 4 and 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 4 recites the limitation "the transgenic mouse animal" in steps c) and d). There is insufficient antecedent basis for this limitation in the claim. Claims 6-8 dependent from claim 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 4, 7 and 8, rejected under 35 U.S.C. 102(a) as being anticipated by Tsuchiya M. (1.21.2003) Therapeutic Antibody Presentation, pgs. 1-21, are no longer anticipated by the instant art because Applicant perfected their foreign priority by providing a certified translation, therefore providing protection against the instant 102(a) art. Therefore, the rejection is withdrawn.

12. Claims 4, rejected under 35 U.S.C. 102(b) as being anticipated by Mancini et al. {Mancini et al. (1993) J. Med. Virol 39 : 67-74}, has been amended to specify that the immunogen is a budding virus particle or part thereof. As Applicant states in their remarks, the instant art does not disclose an immunogen that is a budding virus particle or part thereof. Therefore, the instant art does not anticipate the claims. Therefore, the rejection is withdrawn.

13. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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